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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,028

10/17/2003

Abraham Dijke

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EXAMINER

SODERQUIST, ARLEN

ART UNIT

PAPER NUMBER

1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/688,028

Applicant(s)

DIJKE, ABRAHAM

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119.

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1-23-04 and 11-7-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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1. Applicant's election with traverse of claims 1-17 in the reply filed on November 16, 2006 is acknowledged. The traversal is on the ground(s) that the claims are not materially different since all of the methods include placing a sample on a gel permeation column, eluting the sample to produce fractions and detecting the fractions. This is not found persuasive because the additional limitations provide for different modes of detection. In the elected group of claims a further chromatography step is required prior to detection of at least one of the polycyclic aromatic hydrocarbons and solvents are not specified. In the non-elected groups the additional chromatography step is not required however in the second group a specific solvents and a fluorescence detection step is required to detect a specific polycyclic aromatic hydrocarbon. In the third set of claims individual polycyclic hydrocarbons are not detected, specific solvents are required and the detection is by absorptions rather than fluorescence. Applicant did not indicate that the differences of groups II or III are obvious in view of the limitations of Group I. Thus applicant views the differences as being patentably distinct. And the three groups are patentably distinct having recognizably divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cejpek in view of Williams and Krishen. In the paper Cejpek presents a simplified extraction and cleanup procedure for the determination of PAHs in fatty and protein-rich matrixes. A simplified

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analysis procedure for the determination of 12 priority polycyclic aromatic hydrocarbons (phenanthrene, anthracene, fluoranthene, pyrene, benz(a)anthracene, chrysene, benzo(b)fluoranthene, benzo(k)fluoranthene, *benzo(a)pyrene* (BaP), dibenz(a,h)anthracene, benzo(ghi)perylene and indeno(1,2,3-cd)pyrene) in meat products and other biological materials has been developed. As a first step, ultrasonic extraction with chloroform (a PAH soluble solvent) for isolation of analytes was used. Gel permeation chromatography on Bio-Beads S-X3 utilizing chloroform as mobile phase was applied to remove interferences (lipids, pigments etc.). HPLC with fluorescence detection was employed for quantitation of analytes. Page 69 teaches that water/acetonitrile mixtures were used in the HPLC determination process. Recoveries at a $\mu\text{g/kg}$ (ppb level) spiking level ranged from 53% (phenanthrene) to 112% (benzo(k)fluoranthene) with relative standard deviations in the range of 15% (benzo(k)fluoranthene) to 49% (anthracene). Table 7 shows that the recovery of BaP was at least 99%. Figure 5a shows detection of 0.2 $\mu\text{g/kg}$ (0.2 ppb). Cejpek does not teach the interfacing of the gel permeation chromatography with the HPLC determination apparatus or the use of tetrahydrofuran as the solvent in the gel permeation chromatography process.

In the paper Williams teaches interface development of a non-aqueous size-exclusion chromatography coupled on-line to reversed-phase high-performance liquid chromatography and applications to the analysis of low-molecular-weight contaminants and additives in foods. An interface has been developed which permits the on-line coupling of size-exclusion chromatography in tetrahydrofuran with aqueous reversed-phase high-performance liquid chromatography. The interface isolates the required size exclusion chromatography fraction and dilutes it with water to ensure reconcentration of analytes on the reversed-phase column prior to gradient elution. Operational parameters and the influence of analyte polarity have been examined in detail. A predictive system is presented for determining the applicability of the system to any analyte, based on solute retention times on an ODS phase eluted with a methanol—water gradient. The method is illustrated with examples of direct analyses of crude lipid extracts from a snack product for 2,6-di-tert-4-methylphenol and from chocolate for dibutyl phthalate. Detection limits of ca. 0.5 mg/kg have been achieved. The paragraph bridging pages 316-317 teach that size-exclusion chromatography is closely related to gel permeation chromatography, that gel permeation chromatography has been applied to lipid cleanup for

pesticide analysis and an automated system for this purpose was commercially available. The experimental section on page 317 teaches that the size exclusion material is a poly(styrene-divinylbenzene) material.

In the paper Krishen teaches gel permeation chromatography of low molecular weight materials with high efficiency columns. Improvements in the efficiency of small pore packing materials and column preparation have advanced the speed and convenience of gel permeation chromatography to that of gas chromatography and high speed liquid chromatography. Lack of volatility or the absence of significant differences in polarity, solubility, or ionic characteristics, do not pose problems in this technique. A single column, 610 mm × 8 mm, showed a theoretical plate count of 16,000. By using THF as the eluant at a flow rate of 0.5 mL/min, separations in the molecular weight range of 100-2000 were achieved in <30 minutes. A difference of 1 carbon atom was sufficient for satisfactory resolution of components on the lower molecular weight range. This technique was operated with a dual detection system, differential refractive index and UV absorption at 254 nm, to provide additional information. It was applied to low molecular weight entities encountered in the analysis of plasticizers, antioxidants, various condensation products, and other oligomeric species. Figure 4 shows the separation of epoxidized soy bean oil (triglycerides and fatty acids) from other components using tetrahydrofuran as the eluting solvent. In the experimental section of page 898, the gel used is taught as a polystyrene-divinylbenzene gel.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cejpek in a automated manner as taught by Williams because of the close relationship between size exclusion chromatography and gel permeation chromatography as taught by Williams, the similarity of the column packing material as shown by Williams and Krishen. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use tetrahydrofuran as the elution solvent in the gel permeation separation step of Cejpek as taught by Krishen and Williams because of its ability to separate triglycerides from other types of molecules as shown by Krishen and Williams and the rapidity of that process as taught by Krishen.

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4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art is directed to analysis of PAH and use of gel permeation chromatography.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Arlen Soderquist
Primary Examiner
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